



**MAY 15 2008**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Amnon Talmor  
Regulatory Affairs Specialist  
Synthes (USA)  
1301 Goshen Parkway  
West Chester, Pennsylvania 19380

Re: K080331

Trade/Device Name: Synthes Craniofacial Plate and Screw System  
Regulation Number: 21 CFR 872.4760  
Regulation Name: Bone Plate  
Regulatory Class: II  
Product Code: JEY  
Dated: April 30, 2008  
Received: April 30, 2008

Dear Mr. Talmor:

This letter corrects our substantially equivalent letter of April 30, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0111. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K080331

Device Name: Synthes Orbital Plates

Indications: The Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the midface and craniofacial skeleton, craniofacial surgery, reconstructive procedures and selective orthognathic surgery of the maxilla and chin.

Prescription Use   X    
(Per 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use                       
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K080331

**Sponsor:** Synthes (USA)  
1301 Goshen Parkway  
West Chester, PA 19380  
(610) 719-5000

Amnon Talmor, Regulatory Affairs Specialist  
Phone: (610) 719-6604  
FAX: (484) 356-9682  
talmor.amnon@synthes.com

**Device Name:** Synthes (USA) Craniofacial Plate and Screw System  
**Classification:** Class II per 21 CFR §872.4760;  
Plate, Fixation, Bone; Product Code JEY

**Predicate Device:** Synthes Craniofacial Plate and Screw System

**Device Description:** Synthes Orbital Plates, components of the Synthes Craniofacial Plate and Screw System, consist of anatomically shaped orbital plates that come in various sizes and configurations to fit the patient anatomy. These devices are designed for use with Synthes craniofacial bone screws commercially available in the U.S. System components are manufactured in titanium and are intended for single use only.

**Intended Use:** The Synthes Craniofacial Plate and Screw System is intended for use in selective trauma of the midface and craniofacial skeleton, craniofacial surgery, reconstructive procedures and selective orthognathic surgery of the maxilla and chin.

**Substantial Equivalence:** Documentation is provided that demonstrates the Synthes Orbital Plates are substantially equivalent to other legally marketed devices.